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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/979,533	03/08/2002	Alfred Jann	112843-035	5939

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EXAMINER	
MARX, IRENE	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 12/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/979,533	JANN ET AL.	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 October 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21,23 and 24* is/are pending in the application.

4a) Of the above claim(s) *1-5 and 7-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6,23 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The application should be reviewed for errors. Error occurs, for example in the omission of units regarding the "high molecular weight dextran" in the specification and claims. No new matter may be added.

The amendment filed 10/21/04 is acknowledged. Claims 6 and 23-24 are being considered on the merits.

Claims 1-5 and 7-21 are withdrawn from consideration as directed to a non-elected invention.

Information Disclosure Statement

The initials regarding the article by Roberfroid were inadvertently omitted and are now added. It is noted however that the citation of the article by N.W. Read is incomplete and the citation will not be printed on the face of a patent to be issued from the present application. A corrected signed 1449 form is attached.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6 and 23-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6 and 23-24 are vague, indefinite and confusing in that the nature of the "insulin sensitivity" is not clearly set forth in the instant context. Is this a method of treatment of a medical condition or merely an optional improvement in insulin sensitivity? Moreover, the extent of "increase" of "insulin sensitivity" is not set forth with any particularity. Is it 0.0001%, 0.1%, 1%, 10%, 50%?. No clear indication in this regard is found in the instant specification, particularly with respect to effects or effectiveness of enteral administration as now claimed.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or

with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6 and 23-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for the recitation in claim 6 of "enterally administering a nutritional composition comprising dextran having a molecular weight above about 500,000 and that is administered in an amount from about 2g per day to about 15g per day". The recitation in the specification at page 1, lines 30-33 broadly discloses enteral administration for increasing insulin sensitivity in a mammal, but only mentions a nutritional composition which contains dextran. No indication is provided regarding molecular weight or administration protocol.

Insertion of the limitation "having a molecular weight above about 500,000 and that is administered in an amount from about 2g per day to about 15g per day" does not have support in the as-filed specification. The insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus of "enteral administration" which would show possession of the concept of the use of "dextran having a molecular weight above about 500,000 and that is administered enterally in an amount from about 2g per day to about 15g per day" for the purpose of increasing insulin sensititivy. The exemplified use of dextran is oral administration and for a purpose different from the claim designated purpose. Thus, this is not sufficient support for the new genus of "enterally administering dextran having a molecular weight above about 500,000 in an amount from about 2g per day to about 15g per day". This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate possession of a concept after the fact. Thus, the insertion of "enterally administering a nutritional composition comprising dextran having a molecular weight above about 500,000 and

that is administered in an amount from about 2 g per day to about 15 g per day" is considered to be the insertion of new matter for the above reasons.

This recitation differs substantially from the invention as disclosed.

Therefore, this material constitutes new matter and should be deleted.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant baldly argues that sufficient support and basis for the subject matter is provided for the material claimed in claim 6 citing two separate portions of the specification. However, applicant has failed to point out the nexus between the two cited portions of the specification and a description of "increasing insulin sensitivity in a mammal" by a process comprising "enterally administering a nutritional composition comprising dextran having a molecular weight above about 500,000 and that is administered in an amount from about 2g per day to about 15g per day" . Upon careful reading of the written disclosure, no clear nexus between the two cited portions of the specification. It is not apparent from the instant record that applicant had possession of the concept of "increasing insulin sensitivity in a mammal" by a process comprising "enterally administering a nutritional composition comprising dextran having a molecular weight above about 500,000 and that is administered in an amount from about 2g per day to about 15g per day" at the time the claimed invention was made.

Therefore the rejection is deemed proper and it is adhered to.

Claims 6 and 23-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a process of "increasing insulin sensitivity in a mammal" by a process comprising "enterally administering a nutritional composition comprising dextran having a molecular weight above about 500,000 and that is administered in an amount from about 2g per day to about 15g per day" . However, the written disclosure does not disclose the amount of dextran suitable to be administered enterally as claimed. The broad statement at page 4, lines 4-6

does not indicate that this amount is to be provided enterally and how absorption through the intestine is to be achieved. No clear guidance is provided regarding the preparation and administration of suitable nutritional preparations containing the required amount of dextran to be provided enterally. The only dextran preparations provided are in oral form wherein 3-5 volunteers are provided "Dextran T2000". The relationship between this dextran and the claimed dextran cannot be readily assessed from the instant record. The type of preparation administered is not set forth with any particularity. The only result monitored was the effect of propionic acid in feces upon oral administration of Dextran T2000. Administration is not enteral. The written disclosure suggests that propionic acid concentration in feces increases upon oral administration of dextran. However, there is nothing on the record regarding a nexus or correlation between enteral administration of the recited dextran of high molecular weight in the amounts now claimed and any increase in insulin sensitivity. It is noteworthy that oral consumption of dextran T2000 induced no relevant changes of blood formula, investigated blood proteins or blood plasma enzymes. How is "increase in insulin sensitivity" monitored and on whom? The effects of "enterally administering a nutritional composition comprising dextran having a molecular weight above about 500,000 and that is administered in an amount from about 2 g per day to about 15 g per day" are not addressed in the present written disclosure. There is no clear indication on the record regarding the administration protocol, form or dosages required to achieve the touted effect of "increasing insulin sensitivity" for enteral administration of dextran having a molecular weight above about 500,000 in an amount from about 2g per day to about 15g per day as claimed. Moreover, the effects of added polysaccharides and lipids in enteral nutritional compositions cannot be readily assessed. Also there is insufficient guidance in the written disclosure regarding the making of suitable enteral nutritional compositions as claimed for the desired purpose or how these compositions are to be enterally administered.

Therefore, the claims fail to comply with the enablement requirement, since the claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant argues that the specification discloses that propionate is produced by fermentation of dextran and that propionate is a physiological modulator of fat and glucose metabolism. From these two statements, applicant concludes that "the enteral administration of dextran provides a convenient and simple way of selectively increasing the production of propionate in the gastro-intestinal tract and beneficially modulates physiologic parameters. Accordingly, administration of dextran provides a method for increasing insulin sensitivity". However, these conclusionary remarks fail to demonstrate how to make and use the claimed invention based on the as filed specification. What is lacking in the as filed specification is specific guidelines to achieve a significant increase in insulin sensitivity by the material claimed. Example 3 is directed to the "chronic" administration of 10g per day of dextran T2000 for 10 days. The results of the administration of one dose of 15 g of dextran T2000 is not provided. Moreover, all the results show is an increase in the output of propionic acid. There is no information regarding any increase in insulin sensitivity due to the enteral administration of this type of dextran.

No information is found regarding the protocol necessary to achieve an increase in propionate or how the effect on insulin sensitivity, i.e., whether it is increased and how much, by the enteral administration of dextran in an amount of about 2 g to about 15 g per day as claimed.

Therefore the rejection is deemed proper and it is adhered to.
No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Irene Marx
Primary Examiner
Art Unit 1651